REMARKS

This Amendment is filed in response to the Office Action mailed February 5, 2008 ("*Office Action*"). In this Amendment, claims 85 and 95 are amended, and claims 81-84 and 96-100 are unchanged. Claims 44-47, 54-56, 59-61, 64-80, 86-94 remain withdrawn and claims 1-43, 48-53, 57, 58, 62, and 63 are cancelled. Following entry of this amendment, claims 81-85 and 95-100 shall be pending.

In the *Office Action*, claim 85 is objected to because of an informality, and claims 81-85 and 95-100 have been rejected based on prior art grounds. For the reasons set forth below, these rejections are hereby traversed.

I. CLAIM OBJECTION

The Examiner objected to claim 85 because of a capitalization error. The error has been corrected in the presently amended claim 85. Accordingly, withdrawal of this objection is respectfully requested.

II. REJECTIONS UNDER 35 U.S.C. § 103

Claims 81-85 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,234,456 to Silvestrini ("*Silvestrini.*") in view of U.S. Patent No. 5,258,042 to Mehta ("*Mehta*"). Of these claims, claims 82-85 depend from claim 81. At least for the reasons set forth below, it is submitted that these prior art rejections should be withdrawn and the pending claims allowed.

First, neither *Silvestrini* nor *Mehta*, alone or in combination, teach or suggest activating a reactive material disposed on a device to increase the resistance to blood flow through certain fenestrations of the support device to the aneurysm, as recited in claim 85. In the *Office Action*, the Examiner summarily asserts that activating the hydrophilic material within the hollow fibers 26 of *Silvestrini* "will ***inherently*** reduce flow through the fenestration since the expanded fiber will reduce the size of the opening." At page 3, paragraph 7 (emphasis added). This assertion is insufficient to establish that flow will inherently be reduced through the fenestrations.

> The fact that a certain result or characteristic ***may*** occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. . . . To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. . . . In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic ***necessarily*** flows from the teachings of the applied prior art.

M.P.E.P. at 2112 IV (emphasis added)(internal citations omitted).

In the present rejection, the Examiner has improperly relied on the possibility that expansion of hollow fibers 26 ***may*** result in a decrease in the size of openings 29 of *Silvestrini*. Yet, *Silvestrini* provides no support for the Examiner's assertion. *Silvestrini* merely teaches:

> [T]he hollow fibers 26 of the stent 20, 40 are fabricated of a semi-permeable membrane whose construction is exemplified by polymers that can be formed into semi-permeable membranes as known in the art. . . . The hollow fibers 26 have disposed therein a hydrophilic material, as described above in relation to FIG. 1, which is capable of absorbing a liquid to thereby increase the volume of the material and accomplish its inflation of the fibers 26. . . . The stent 20, 40 is positioned as described above in relation to FIG. 1 at its desired site within the lumen. Likewise, this position is maintained by the delivery means at the site of desired placement for a period of time sufficient to permit the diffusion of an adequate amount of surrounding tissue fluids into the fibers 26 to thereby swell the hydrophilic material and inflate

> the stent 20, 40 so that it independently remains in place by impinging on the interior lumen wall. Of course, the semi-permeable membrane employed to fabricate the hollow fibers 26 must be of sufficient strength to resist rupture from the pressure there within created by the expanded hydrophilic material. Tissue ingrowth occurs through the radial openings 29.

At column 3, line 40 through column 4, line 2. As one of ordinary skill in the art would recognize, hollow fibers 26 would be susceptible to at least two forms of expansion, lengthening of the fiber and thickening of the fiber. Furthermore, it would be recognized that the actual effect of expansion on the inflated characteristics of the stent and, by implication, the size of openings 29 would be a function of the combination of these two types of expansion. For example, expansion of the stents of *Silvestrini* may predominantly lengthen the hollow fibers 26, thereby allowing the stents to increase in overall diameter and impinge the interior lumen wall. *See e.g.* column 2, lines 48-58. Intuitively, expansion that predominantly makes the hollow fibers 26 longer would result in an accompanying *increase* in the size of openings 29.

In fact, *Silvestrini* fails to teach any details with respect to these factors and, significantly, makes no mention of a change in the size of the radial openings 29 as a result of the expansion of the stent. *Silvestrini* only teaches that the openings 16 and 29 are important for tissue ingrowth. At column 2, lines 62-64 and column 3, lines 38-41. As such, restriction or shrinking of the openings 29, as suggested by the Examiner, would appear contrary to achieving this objective.

For at least the above reasons, it is submitted that the Examiner has improperly read into, and/or claimed inherent, an element of the presently claimed invention that is simply not taught or made obvious in *Silvestrini*. *Mehta* also fails to make up for the above described deficiency of *Silvestrini*. *Mehta* is directed towards a tubular stent, and makes no mention of the presence of openings, fenestrations, or a change in size of such features. At column 4, lines 19-20.

Considering the above, it becomes self-evident that claim 81 of the present application is neither taught or made obvious by the cited prior art. Accordingly, withdrawal of the present rejection is respectfully requested.

Turning now to claims 82-85, these claims depend from claim 81 and are allowable for at least the same reasons as claim 81. Accordingly, withdrawal of the present rejection is respectfully requested. However, these claims further limit the claimed invention and are, thus, separately patentable over the cited prior art.

Claims 95-100 are also rejected under 35 U.S.C. § 103(a) as being unpatentable over *Silvestrini* in view of *Mehta* and further in view of U.S. Patent No. 6,090,911 to Petka et al. ("*Petka et al.*"). Of these claims, claims 96-100 depend from claim 95. It is submitted that these prior art rejections should be withdrawn and the pending claims allowed for the following reasons:

First, amended claim 95 recites, in part, allowing the hydrogel to change from its first state of protonation to its second state of protonation, thereby resulting in expansion of the hydrogel and lessening of the size of the adjacent fenestrations, and thereby increasing the resistance to blood flow through those fenestrations to the aneurysm. As described above, neither *Silvestrini* nor *Mehta*, alone or in combination, teach or suggest lessening of the size of the adjacent fenestrations, and thereby increasing the resistance to blood flow through those fenestrations. Furthermore, *Petka et al.* also fail to overcome these deficiencies. *Petka et al.* are directed towards copolymers that form solutions that can reversibly gel under certain conditions and the biological synthesis thereof. ABSTRACT. *Petka et al.* fail to teach stents, openings and fenestration in stents, or a change in the size of such features.

Second, amended claim 95 also recites, in part, a stimulus expandable hydrogel having a first state of protonation prior to implantation in the blood vessel and undergoing a predetermined controlled rate of change to a second state of protonation after implantation in the blood vessel. While the Applicant does not believe this claim amendment necessary to overcome the present rejection, the amendment is presented to further distinguish the claimed invention from the prior art and to accelerate

prosecution. Support for this amendment can be found at paragraph [0049] of the present application.

While *Petka et al.* do teach certain general characteristics of hydrogels, *Petka et al.* fail to teach a pretreatment for such hydrogels that achieves the claimed controlled rate to change. As cited by the Examiner, at column 9, lines 28-43, *Petka et al.* teach that:

> Hydrogels belong to a class of functional materials that respond to a variety of stimuli in aqueous environments. They can be designed to swell or shrink under certain physiological conditions (e.g., at high or low salt concentration, pH, or temperature) and they can be used to encapsulate cells, drugs, and other molecules for site specific use. For example, since the random coil groups can include charged groups (e.g., repeated segments that include glutamic acid residues), the gels can swell or shrink depending on whether the conditions stabilize or destabilize the charges. In the example in which the segments include many acidic residues, increases in the pH would result in an increased number of deprotonated carboxylic acid residues, thus increasing charge--charge repulsion and causing the gel to swell. Conversely, decreases in pH would protonate the carboxylic acid residues and allow the gel to shrink.

It would be understood by one of ordinary skill in the art, that this is merely a statement of what is generally true regarding a hydrogel, i.e. that a hydrogel's characteristic to shrinking or swelling may be a function of the hydrogel's composition of acidic or basic side groups; the subsequent protonation or deprotanation of these side groups being a mode of action for such shrinking or swelling.

The Applicant's present invention goes beyond these known characteristics of hydrogels to achieve a programmed or controlled rate of expansion of the hydrogel. At paragraph [0049] the Applicant describes an example of an embodiment in which a hydrogel including acid side groups is incubated in a low pH solution for 70 hours at

37 C, the incubation solution is washed, and the hydrogel is dried. Once implanted in vivo, the hydrogel becomes fully expanded after approximately 1 hour at physiological pH 7.4. This is merely an example showing how the hydrogel may be pretreated to achieve a desired response rate. U.S. patent application Serial No. 09/804,935, which is incorporated by reference into the present application, describes that the duration and temperature of the incubation is directly proportional to the amount of expansion control achieved. At ¶ [0030]. The low pH incubation functions to more effectively protonate the hydrogel's acid side groups prior to deployment within a physiological system. *Id.* This, in turn, effectively slows or delays expansion because more of the hydrogel's acid side groups must be deprotonated prior to contributing to the expansion of the hydrogel. *Id.* For example, while a 37 C incubation for 70 hours results in full expansion of the hydrogel within approximately one hour, incubation at the same temperature for 22 hour results in full expansion after approximately 15 minutes at physiological pH 7.4. At ¶ [0042].

In contrast, *Petka et al.* make no mention of a controlled rate of change, expansion, or any other characteristic of the taught copolymers. Accordingly, *Petka et al.* do not teach or make obvious the Applicant's claimed controlled rate of change. Similarly, *Silvestrini* and/or *Mehta* also fail to teach or make obvious a controlled rate of change.

Considering the above, it becomes self-evident that claim 95 of the present application is neither taught or made obvious by the cited prior art. Hence, withdrawal of the present rejection is respectfully requested.

With respect to claims 96-100, these claims depend from claim 95 and are allowable for at least the same reasons as claim 95. Accordingly, withdrawal of the present rejection is respectfully requested. However, these claims further limit the claimed invention and are, thus, separately patentable over the cited prior art.

CONCLUSION

In view of the foregoing, it is submitted that pending claims 81-85 and 95-100 are now in condition for allowance. Hence an indication of allowability is hereby requested.

If for any reason direct communication with the Applicant's attorney would serve to advance prosecution of this case to finality, the Examiner is cordially urged to call the undersigned attorney at the below listed telephone number.

The Commissioner is authorized to charge any fee which may be required in connection with this Amendment to deposit account No. 50-2809.

Respectfully submitted,

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